

REMARKS

Claim 1 has been amended to correct an obvious spelling error. Claims 7 and 14 have been amended to more clearly define that which Applicants regard as the invention. Support for amendments to Claims 7 and 14 can be found in the specification. For example, page 6, lines 7-9 describes an embodiment in which the dispensing assembly includes dispensing actuators. Additionally, page 3, lines 27-28 describes an embodiment in which the liquid dispensing station is stationary.

Claims 1 and 8 have been amended to avoid any misunderstanding of the claims in view of a recent decision, *Cytologix Corp. v. Ventana Medical Sys., Inc.*, No. 04-11783-RWZ (D. Mass. 2006), a copy of which is attached. As stated on page 3, lines 25-28, “To provide the relative movement, either the liquid dispensing station, or the platform, or both may move. In one embodiment, the liquid dispensing station is stationary and the platform moves to index slides to the liquid dispensing station.” “[R]elative movement between the liquid dispenser and platform” could result from either the liquid dispenser or the platform, or both, moving relative to the instrument base. Movement of either as the other remains stationary relative to the instrument base causes relative movement between the liquid dispenser and platform.

Entry of the amendments is respectfully requested.

Claims 1, 3, 5-8, 10, and 12-14 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,183,693. A terminal disclaimer results in no reduction in term and is being filed herewith as to U.S. Patent No. 6,183,693 to expedite prosecution by obviating the obviousness-type double patenting rejection and is not an admission as to obviousness.

Claims 1, 3, 5-8, 10, and 12-14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Heidt *et al.*(USP 5,089,229), Copeland *et al.* (USP 5,654,200), Kerr *et al.*(USP

5,075,079), or Rogers *et al.* (USP 4,043,292) in view of Potter *et al.* (USP 5,819,842). The Examiner stated that Heidt, Copeland, Kerr, or Rogers “teach a plurality of slides heated by a plural heated means” and that “Potter *et al.* teach in the abstract and columns 1-2 that it is desirable to heat slides independently based on the specific reaction/conditions required for each slide.” (Note that not all of the claims of the present application are directed to heating a single slide; in fact, only dependent claims 3 and 10 are directed to a heated surface area adapted to support only one slide.) None of the cited references teach, suggest, or disclose a dispensing assembly having a platform with plural heated surface areas, each heated by an electric heater thereunder, and a liquid dispenser wherein the liquid dispenser and platform are adapted for relative movement with respect to each other. Additionally, none of the references offer a motivation to combine Heidt, Copeland, Kerr, or Rogers with Potter.

The Examiner previously rejected Claims 1-2, 4-9, and 11-14 under 35 U.S.C. §102(e) as anticipated by the four primary references cited in the current Office Action. As argued in the Amendment and Statement of Substance of Interview filed on January 20, 2006 in response to the previous Office Action, none of these four primary references disclose, teach, or suggest a platform supporting a plurality of microscope slides, the platform having plural heated surface areas, each heated by an electric heater thereunder, as described in the claims. Nor do any of the four primary references teach plural temperature sensors on the platform for sensing temperature of respective heated surface areas as described in the claims. The Examiner has apparently relied on Potter for these elements since Potter is newly cited for combination with the previously cited references. However, Potter discloses neither a slide handling device, nor a liquid dispenser and microprocessor as described in the claims. Additionally, as described below, it would not have been obvious to one of skill in the art to combine any of the primary references with Potter.

The Potter reference discloses an apparatus capable of independently regulating the heating of all samples in a sample container designed for rapid heat transfer to a set temperature. According to FIGS. 1 and 2 of Potter, within the sample plate 10, the sample 11 is in the form of a thin disc of fluid contained in a well 13. Each well 13 is sealed at the top by sealing foil 15 and

sticky seal 17 or heat sealed after the samples 11 are placed in them. The base of the well 13 is likewise shielded.

Potter does not teach, disclose, or suggest a dispensing assembly comprising a platform having plural heated surface areas, heated by an electric heater thereunder, wherein the platform and a liquid dispenser are adapted for relative motion with respect to each other. Nor does Potter teach, disclose, or suggest plural heated surface areas being adapted to be in contact with and underlie a microscope slide. Nor would it be obvious, for reasons presented below, to combine the Potter reference with one having those features.

As was discussed in the interview with Examiner Alexander on January 10, 2006 and explained in the Amendment and Statement of Substance of Interview, “the present invention was developed to enable random access processing of multiple microscope slides in different ways by applying the reagent to selected slides and selectively heating the slides.” An apparatus without a liquid dispenser would not be suitable for random access processing. Thus, one of ordinary skill in the art would not have been motivated to combine Potter’s apparatus, without a liquid dispenser, with any of the primary references cited by the Examiner.

MPEP §2141 states that “references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination” when considering an obviousness rejection under 35 U.S.C. § 103. The Court of Customs and Patent Appeals summarized this requirement as follows:

The ever present question in cases within the ambit of 35 USC 103 is whether the subject matter as a whole would have been obvious to one of ordinary skill in the art following the teachings of the prior art at the time the invention was made. It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.

In re Herman Wesslau, 353 F.2d 238, 241 (CCPA 1965). The Potter reference requires closed wells, and it is impermissible to exclude those closed wells in an attempted combination with the references. Not only do the references not suggest the desirability of the combination, Potter teaches away from the combination.

The apparatus disclosed by Potter is designed to be used in carrying out enzyme reactions, hybridization and melting of nucleic acids, and thermal cycling of samples for amplification of DNA. These types of laboratory techniques require small amounts of expensive reagents or difficult to obtain samples. As such, one of the primary concerns is reduction of evaporation while the samples are being heated and cooled. To prevent condensation and evaporation of the sample, the top of the sample container is covered with a lid that has heating elements. (See column 7, lines 6-12.) Consequently, at least in part to minimize evaporation and condensation, Potter discloses that “samples 11 are contained in wells 13 of low thermal mass... These wells 13 are sealed at the top by sealing foil 15 and sticky seal 17 or heat seal after the samples 11 are placed in them.” (Column 3, lines 61-65). Such a system is incompatible with the systems of the other references and with the system disclosed in the present application. Since the samples would be inaccessible to the dispensing assembly after the sealing foil 15 was applied, the apparatus described in Potter would not be useful for histochemical staining. Histochemical staining of biological samples requires sequential application of at least one stain and a wash solution to remove the excess stain. Actually, almost all histochemical processes require multiple stains or reagents, interspersed by washes. A system in which the samples are sealed off from the outside environment after being placed on the apparatus would not be compatible with the needs associated with staining protocols. Thus, one of skill in the art would not look to Potter when designing a dispensing assembly wherein liquid reagents are dispensed onto the slides from above as claimed in the present invention.

The heating of samples to different temperatures in Potter resulted from the particular requirements related to carrying out enzyme reactions, hybridization and melting of nucleic acids, and thermal cycling of samples for amplification of DNA. In these types of chemical reactions,

all of the reactants are added, the container is sealed, and the mixture is then heated. This is an important difference to the multi-sequential process steps associated with histochemical stains. Because of the need for sealed sample containers to allow for the use of very small amounts of reagents, automated systems with overhead dispensers such as in the primary references are not suited to the kind of device described in Potter. The primary references, Copeland and Rogers, on the other hand, do not relate to these laboratory techniques but would have been seen by one skilled in the art as being particularly suited to histochemical staining. The types of stains that were intended for use with the instruments shown in Copeland and Rogers all heated to the same (low) temperature. The primary references, Heidt and Kerr, on the other hand, also do not relate to the laboratory techniques described in Potter, but would have been seen by one skilled in the art as being particularly suited for use with chemical analyte slides which also do not require heating to different or higher temperatures. Accordingly, one of ordinary skill in the art would not have modified the apparatus disclosed in any of the primary references to incorporate the heating of samples to different temperatures as disclosed in Potter.

Furthermore, Potter describes a heating block adapted for specially designed microplate wells containing liquid samples. Potter does not describe staining of tissue sections on microscope slides. Potter makes no mention of slides, histochemistry, or tissue samples. Instead, Potter relates to analyzing a liquid sample 11. (Column 3, lines 55-56.) Instead of microscope slides, the samples are in wells 13, such as in a microplate format. (Column 3, lines 61-63; Column 7, lines 5, 11, and 18-21; Fig. 1.) Unlike a transparent and rigid microscope slide, Potter teaches that the sample is placed on a thermally conductive foil 12. (Column 3, lines 56-58.) Metal foils are neither transparent nor rigid. These differences emphasize the fact that Potter discloses an apparatus for uses that are quite different from histochemical staining of tissue samples. Therefore, the reasons stated in the specification of Potter, (Column 1, line 9 through Column 2, line 29), regarding the desirability for varying the temperature of samples must be viewed in the context of liquid biological samples, and does not translate to slide staining. The teachings of Potter do not provide a motivation to one of ordinary skill in the art of slide staining to combine Potter with the cited primary art references.

As discussed above, a prior art reference must be considered as a whole. To function as described in the specification, the apparatus disclosed by Potter necessarily includes a fixed, closed container and requires selective heating. The primary references, on the other hand, describe systems that dispense reagents onto open slides where generalized heating to relatively low temperatures is sufficient. If one of ordinary skill in the art wanted to gain the automation advantages disclosed in the primary references for use with the types of laboratory techniques described by Potter, then one would have to modify the primary references to accommodate the needs of those laboratory techniques; that is, at a minimum, the sample container would be designed to minimize evaporation and condensation. One of ordinary skill, however, considering the inefficiency of implementing such a system, would be strongly disinclined to combine the automatic dispensing features of the primary references with the closed container approach of Potter. When the disclosure of Potter is considered as a whole, it teaches away from any combination with the primary references.


Accordingly, it is submitted that none of the references, alone, or in combination, teach, suggest, or disclose, plural heated surfaces, heated by an electric heater thereunder, on a moving platform which carries microscope slides to a dispensing station. Thus, the rejection under 35 U.S.C. §103(a) is respectfully traversed and reconsideration is requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 04-11783-RWZ

CYTOLOGIX CORPORATION

v.

VENTANA MEDICAL SYSTEMS, INC.

MEMORANDUM OF DECISION

June 20, 2006

ZOBEL, D.J.

Plaintiff CytoLogix Corporation sued defendant Ventana Medical Systems, Inc. for infringement of U.S. Patent No. 6,541,261 B1 (the "261 patent") and U.S. Patent No. 6,783,733 B2 (the "733 patent"). These patents concern "technology for staining tissue samples in connection with the diagnosis of diseases such as cancer." (Pl.'s Mem. in Support of Summ. J. and Claim Construction 1). Plaintiff accuses defendant's Benchmark instrument product line of infringing these patents and now moves for claim construction and summary judgment on claims 1 and 2 of the '261 patent. Defendant opposes.

The first claim of the '261 patent describes a method for processing samples mounted on microscope slides that are placed on a platform. See '261 Patent 12:14-25. In addition to other characteristics, the method provides for "moving the platform and a liquid dispenser relative to each other." Id. at 21-22. The second claim of the '261 patent depends from claim 1 and describes the same method with the

distinction that “each heating element heats only one slide.” Id. at 26-28. The parties dispute the meaning of the language, “moving the platform and a liquid dispenser relative to each other,” and each party bases its summary judgment argument on its proposed claim construction. According to plaintiff, the disputed language means that “[t]here is relative movement between the platform and the liquid dispenser. Relative movement may be accomplished by moving the platform, or the liquid dispenser, or both.” (Pl.’s Mem. in Support of its Combined Mot. 7). Defendant, on the other hand, urges that “[t]his claim language requires moving both ‘the platform’ and ‘a liquid dispenser.’ It does not permit moving only one of them.” (Def.’s Mem. in Opp. to Pl.’s Combined Mot. 6). Giving rise to the dispute are certain of defendant’s slide processing products that – solely for purposes of arguing the instant motion, the parties agree – involve a mobile liquid dispenser but a stationary platform.

“[P]atent infringement analysis involves two steps: claim construction, and application of the construed claim to the accused product or process.” Wilson Sporting Goods Co. v. Hillerich & Bradsby Co., 442 F.3d 1322, 1326 (Fed. Cir. 2006). The first step, claim construction, requires that the Court construe “only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.” Vivid Technologies, Inc. v. American Science & Engineering, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999). “[T]he words of a claim ‘are generally given their ordinary and customary meaning,’” in other words, “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” Phillips v. AWH Corp., 415 F.3d 1303, 1312-13

(Fed. Cir. 2005). A disputed claim term may be interpreted according to “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” Id. at 1314.

Plaintiff relies, first, on the plain language of the disputed claims and argues that the phrase, “relative to each other,” requires only that either the platform or the dispenser move, since either event would create relative movement. As defendant argues, however, this interpretation negates the conjunctive term “and,” as used in the phrase, “moving the platform and a liquid dispenser relative to each other.” Plaintiff’s expert, Professor Alexander H. Slocum, explains the term “and” from the perspective of an individual with ordinary skill in the art – for example, an engineer with basic training in physics – as creating reciprocal frames of reference. The platform is the frame of reference for whether the dispenser moves, and the dispenser is the frame of reference for whether the platform moves. (See Slocum Aff. ¶ 9). Even if, in fact, the platform is static and only the dispenser moves, a tiny observer standing on the platform who sees the moving dispenser would not know whether to attribute the motion she observes to the platform or the dispenser. Thus, at least in theory, both the dispenser and the platform are moving relative to each other. The perspective is similar to that of a passenger who sits on a stationary northbound train next to a stationary southbound train on adjacent tracks. When one or both of the trains begin moving, the passenger will comprehend motion but will not know whether it is his train alone, the southbound train alone or both trains together that are moving.

The difficulty with this position is that it does not account for a third frame of reference created by the requirement that something or someone be “moving” the platform or dispenser. In describing a method of moving the platform or dispenser, the claim language adopts the perspective of the person or thing responsible for causing this movement, not the theoretical perspective of an observer sitting on either the platform or dispenser. While such a theoretical observer may be unable to discern whether movement comes from the dispenser or the platform, the person or thing responsible for moving the platform and dispenser will have this knowledge.

Defendant’s expert, Professor Geoffrey Nunberg underscores this understanding from the view of a linguist interpreting the disputed claim language according to rules of grammar. However, “one of ordinary skill in the art” generally refers to an individual with expertise in the field of the patented invention, not someone skilled in the field of language and drafting. See Phillips, 415 F.3d at 1333 (explaining that “[f]or each patent, for example, who qualifies as one of ordinary skill in the art will differ, just as the state of the art at the time of the invention.”). Thus, while interesting, Professor Nunberg’s testimony is not representative of a person of ordinary skill in the art, and I do not rely on his opinion in resolving the instant dispute.

Plaintiff next argues that its interpretation of the language in claim 1 is more consistent with the articulation of dependent claims in the '261 patent. Plaintiff focuses on claim 3 that describes a “method of processing samples . . . wherein the platform is a moving platform capable of indexing slides adjacent to a stationary liquid dispensing location.” '261 Patent 12:29-32. According to plaintiff, depiction of the platform as

"moving" necessarily implies that the platform may otherwise be immobile. Defendant counters that the purpose of claim 3 is not to identify the platform as moving, but to provide that it be "capable of indexing slides adjacent to a stationary liquid dispensing location." Defendant also relies upon claim 7 that references "said moving platform" and, thereby, implies that the "said" platform portrayed in claim 1 is mobile. Plaintiff asserts that this language resulted from a clerical error that should have been, and will eventually be, amended. "An error in the prosecution record must be viewed as are errors in documents in general; that is, would it have been apparent to the interested reader that an error was made, such that it would be unfair to enforce the error." Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc., 249 F.3d 1341, 1348 (Fed. Cir. 2001). Because nothing suggests that an interested reader would have understood the inclusion of the term "said" to be in error, claim 7 should be read as originally drafted.

The patent specification further supports defendant's position, as the parties agree that none of the preferred embodiments describe a stationary platform. Plaintiff correctly notes that the embodiments do not foreclose the possibility of a stationary platform, but they certainly do not support an interpretation of the claim language as describing a stationary platform. While the Federal Circuit "ha[s] repeatedly warned against confining the claims to [very specific] embodiments" and "strictly limiting the scope of the claims to the embodiments disclosed in the specification," it has also discouraged "divorcing the claim language from the specification." Phillips, 415 F.3d at 1323-24. Appropriate interpretation will consider the full context of the patent. See id.

Turning from the platform, plaintiff focuses on the first preferred embodiment's description of the liquid dispenser. The embodiment describes a stationary hammer that helps push liquid from the dispenser onto a slide. See '261 Patent 5:25-51. In order to define the dispenser as including a stationary element, plaintiff characterizes the hammer as part of the liquid dispenser. However, the patent specification defines the hammer as part of the dispensing station, not the dispenser, and plaintiff offers no rationale for a different characterization. See id. 5:25-26 (providing that "the dispensing station comprises a soft hammer . . .").

The file history of the '261 patent also favors defendant. It reveals amendments to the language in claim 1 that include replacing the term "moving platform" with "moving the platform and a liquid dispenser relative to each other." (Pl.'s Mem. in Support of Summ. J. and Claim Construction 10-11). Plaintiff believes that this change underscores the importance of relative motion and the ability to accomplish such motion between the platform and the liquid dispenser without having a moving platform. (Id.). This understanding is inconsistent, however, with the repeated description of "moveable slides" and the use of a carousel in describing the platform, as cited by defendant. (See Def.'s Mem. in Opp. to Pl.'s Combined Mot. 19-24). Plaintiff argues that independent slide heating, and not movability, constituted the Examiner's focus on the patent, so that use of these terms occurred only in passing, not deliberately. Even assuming *arguendo* that plaintiff is correct, "a patentee's statements during prosecution, whether relied on by the examiner or not, are relevant to claim interpretation." Microsoft Corp. v. Multi-Tech Systems, Inc., 357 F.3d 1340, 1350 (Fed.

Cir. 2004). Plaintiff also posits that the term moveable “was appropriate, given that the movement had already [sic] been defined as relative to the liquid dispenser.” (Pl.’s Mem. in Support of Summ. J. and Claim Construction Footnote 4). This reasoning cannot provide additional support for plaintiff’s position, because it necessarily presumes that plaintiff’s argument for relative motion would prevail and thus is circular.

In light of the applicable legal standard, the parties’ written submissions, and the argument of counsel, I construe the disputed claim language as follows:

| Term | Court’s construction |
|---|--|
| Moving the platform and a liquid dispenser relative to each other | Moving both the moveable platform and a moveable liquid dispenser relative to each other |

Plaintiff’s Motion for Summary Judgment (#42 on the docket) is denied.

06/20/06

DATE

/s/ Rya W. Zobel

RYA W. ZOBEL

UNITED STATES DISTRICT JUDGE